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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/076,902

Examiner

Shaojia A. Jiang

Applicant(s)

CHERR ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 38, 45-48 and 53-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-37, 39-44 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's claim for domestic priority to provisional application Serial No. 60/349,144 under 35 U.S.C. 119(e) is acknowledged.

The provisional application 60/349,144 upon which priority is claimed, appears to provide adequate support under 35 U.S.C. 112 for the claims in this application.

Election/Restrictions

Applicant's election without traverse of the invention of Group II, Claims 35-37, 39-44 and 49-52 in Paper No. 6, submitted June 26, 2003 is acknowledged.

Claims 1-34, 38, 45-48, and 53-55 and are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 35-37, 39-44 and 49-52 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37, 39, 42, 43-44, 49, and 51 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular sulfonated compound in claim 37 (e.g., a lignosulfonic acid, also known as a lignosulfonate, ligninsulfonate, lignosulfate, or poly(lignosulfonic acid, see the other

names of lignosulfonic acid provided by STN Registry, PTO-892), in combination with the only one particular spermicide, Nonoxynol 9TM (see page 6 line 1 of the specification herein) with or without a sperm, in pharmaceutical compositions herein, does not reasonably provide enablement for any sulfonated compounds isolated from a natural source or any derivatives of a lignin in claims 49 and 51, and any compounds having spermicide function (i.e., in claims 39 and 43).

One skilled in the art would clearly recognize that any sulfonated compounds isolated from a natural source would encompass numerous or may be a million different compounds having various structures and possessing very different functional properties or activities. Moreover, the recitation, spermicide, is seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

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The nature of the invention: The instant invention pertains to compositions used for inhibiting fertilization or contraception.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the broadest claim (i.e., claims 37, 39, 43, 49, and 51) reads on any sulfonated compounds isolated from a natural source or any derivatives of a lignin in claims 49 and 51, and/or any compounds having spermicide function employed in the composition herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does “little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate”. The CAFC further clearly states that “[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials” at 1405(emphasis added), and that “It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus..” at 1406 (emphases added).

In the instant case, as discussed above, "spermicide", recited in the instant claims is purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. Moreover, as discussed above, a skilled artisan would clearly recognize that any sulfonated compounds isolated from a natural source would encompass numerous or may be a million different compounds having various structures and possessing very different functional properties or activities. However, the specification merely provides particular sulfonated compounds (e.g., in claims 35 and 37) and one particular compound for spermicide, Nonoxynol 9™.

Thus, the instant specification fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph, since it fails to provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the

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genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.*

Regarding “a derivative of a lignin”, it is known that not any derivatives of lignin are bioactive or having pharmaceutical activities, but only those ligin-derived macromolecules (LDM) containing lignosulfonate or sulfonated (or sulfated) derivatives according to the teachings of Pillai et al. (see abstract and page 140-141, “34” in PTO-1449 submitted November 25, 2002). Cherr et al. also teaches that those low molecular weight polar compounds in the fraction in the isolation of LDM from liginin, are not bioactive (see the bottom of the right column at page 523, “17” in PTO-1449 submitted November 25, 2002). Thus, not all derivatives of lignin have enablement for the instant invention.

Moreover, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any sulfonated compounds isolated from a natural source or any derivatives of a lignin, and any compounds having spermicide function in the pharmaceutical compositions herein.

Further, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (e.g., a male or a female, or *vivio*) the **combination** of any compounds represented by any sulfonated compound isolated from a natural source or any derivative of a lignin, and any compound having spermicide function in a composition. See text book “Goodman &

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Gilman's The Pharmacological Basis of Therapeutics" regarding possible drug-drug interactions (9th ed, 1996) page 51 in particular. This book teaches that "The frequency of significant beneficial or adverse drug interactions is unknown" (see the bottom of the left column of page 51) and that "Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed" and that "The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can have significant adverse consequences" (see the right column of page 51) (emphases added). Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

It is noted that only two particular sulfonated compounds, a lignosulfonic acid (LSA) and polyanetholesulfonic acid (PASA) were tested in working examples in the specification (see page 21-30). Thus, the specification fails to provide sufficient support of the broad use of any sulfonated compounds isolated from a natural source or any derivatives of a lignin in claims 49 and 51, and any compounds having spermicide function, recited in the claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions, with no assurance of success.

Claim Objection

Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim since the particular polysulfonated compound, e.g., polyanetholesulfonic acid, has been recited already in claim 35, the independent claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 37, 49 and 51-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations, "derivatives thereof" in the end of claims 35 and 37 and "a derivative thereof" in the end of claim 49, render claims 35, 37, 49 and 52 indefinite. These recitations are not defined in the specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to "derivatives thereof", since one of ordinary skill in the art would clearly recognize so many various and possible derivatives. Therefore, the scope of claims is indefinite as to the encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-36, 39-42 and 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Pillai et al. ("34" in PTO-1449 submitted November 25, 2002).

Pillai et al. discloses a composition or compositions comprising lignin-derived macromolecules (LDM) containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, and a sperm in an aqueous solution (a pharmaceutical excipient) in varying concentrations, wherein LDM may inhibit the sperm acrosome reaction (see page 140, "Introduction" lines 1-4 and the last seven lines of "Introduction", the

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particular tested samples at page 142, entitled "2.5 Effect of LDM and electroeluted LDM bands on sperm acrosome reaction" the 1st paragraph, and the last three lines at page 144, and the 2nd paragraph of page 145). It is noted that lignin is known from a woody plant (see the definition of lignin - its ordinary and customary meaning provided by the American Heritage Dictionary, Second College Edition, 1982, page 730, PTO-892; see also US 5,698,524 abstract, PTO-1449 submitted November 25, 2002).

Thus, the disclosure of Pillai et al. anticipates claims 35-36, 39-42 and 49-50.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. ("16" in PTO-1449 submitted November 25, 2002).

Anderson et al. discloses a composition or compositions comprising the particular polyvinylsulfonic acid derivative, poly(styrene-4-sulfonate (N-PSS, therein), and a sperm in an aqueous solution (a pharmaceutical excipient) in varying concentrations, wherein N-PSS may disrupt the sperm acrosome (see abstract, page 864 the last paragraph, and the particular tested samples at page 865, the left column). Thus, the disclosure of Anderson et al. anticipates claims 35-36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37, 43-44, and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pillai et al. ("34" in PTO-1449 submitted November 25, 2002) and Anderson et al. (6,063,773, PTO-892).

The same disclosure of Pillai et al. has been discussed above (see supra at page 9-10).

Anderson et al. (6,063,773) discloses that the known spermicide, nonoxynol-9, is known to be useful in a pharmaceutical composition for contraception or inhibiting fertilization. See abstract, col.1 lines 23-32 and col.3 lines 13-16 in particular.

Pillai et al. and Anderson et al. do not expressly disclose the employment of a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a lignosulfonate or a lignosulfonic acid in combination

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with a spermicide such as nonoxynol-9 in a pharmaceutical composition since both a lignosulfonate or a lignosulfonic acid, and the known spermicide, nonoxynol-9, are known to be useful in a composition for contraception or inhibiting fertilization based on the cited prior art. Therefore, one of ordinary skill in the art would have reasonably expected that combining a lignosulfonate or a lignosulfonic acid and nonoxynol-9, both known useful for the same purpose, would improve the therapeutic effects for contraception or inhibiting fertilization, and/or would produce additive therapeutic effects in treating the same. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) regarding combination inventions. It is considered prima facie obvious to combine two active composition components into a single composition to form a third composition useful for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. .

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

A handwritten signature in black ink, appearing to read 'S. Anna Jiang', is positioned above the printed name.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
July 12, 2003